DETAILED ACTION

1. This Office Action is responsive to the Amendment filed 5 July 2007. Claims 1-23 and 25-28 are now pending. The Examiner acknowledges the amendments to claims 1, 9 and 22, as well as the addition of claim 28.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1-4, 6-9 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Silverman (US Patent 6251063) in view of Bley (US 6592859). Silverman et al. ('063) teaches a method comprising: implanting a bulking prosthesis (337,371) in tissue proximate to an anal sphincter (356) (as seen in Figure 19, 21 and 22) using a tubular instrument (31) (as seen in Figure 7), wherein the tissue comprises at least one of a submucosa and a musculature (202) underlying the submucosa (as seen in Figure 9 of Silverman et al.). Silverman et al. further teaches that implanting the bulking prosthesis (337,371) comprises: penetrating a mucosa (196) proximate to the tissue with a syringe (366) needle (368) (as seen in Figures 21 and 23 of Silverman et al.) thereby forming a hole in the mucosa (196); drawing a mucosa (196) away from a musculature (201) underlying a submucosa (as seen in Figures 7 and 9);

forming a pocket (227) in one of the submucosa and the musculature (201); and implanting the bulking prosthesis (337,371) in pocket (227) (as seen in Figures 7 and 9) (as described in lines 30-37 and 64-67 of column 15 of Silverman et al.), through the syringe (366) needle (368) (as described in lines 21-26 of column 28 and 13-19 of column 29 of Silverman et al.), wherein the stability and configuration of the implant should be observed over time and may require further procedures to supplement previously formed implants (as described in lines 18-20 of column 19). While Silverman et al. teaches that said bulking prosthesis (337,371) comprises materials including silicone, collagen and the injection of solutions which form precipitates (as described in lines 28-44 of column 27), it is not taught that the bulking prosthesis (337) enlarges after implantation.

Bley teaches a method of implanting a bulking prosthesis in the tissue of a patient, wherein said bulking prosthesis is in a miniature state at the time of implantation and assumes an enlarged state after implantation, wherein said bulking prosthesis comprises a hydrogel (as described in lines 29-38 of column 2). Bley further teaches that materials such as collagen and silicone are known to break down, migrate and are often absorbed by the body (as described in lines 55-67 of column 1 and in lines 1-5 of column 2). Additionally, Bley teaches that the injection of solutions having liquids which dissipate have the disadvantage that the final size of the implant is hard to predict, often forcing a surgeon to inject either significantly more of the solution then they thought necessary and/or results in too little material being injected (as described in lines 26-53 of column 1), wherein additional injections are often required. However, using solid

materials that swell after injection or implantation have an advantage in that their final size is more predictable because they swell to a size equal to that of the cavity created during the injection, thus they don't migrate away from the injection site (as described in lines 47-67 of column 6). It would have been obvious to one of ordinary skill in the art at the time of the invention to use a bulking prosthesis similar to that of Bley in a method similar to that of Silverman et al. in order to treat fecal incontinence in view of the teachings of Bley because a bulking prosthesis similar to that of Bley has a more predictable size after injection, is permanent and won't degrade or be absorbed by the body like collagen and silicone, thus eliminating the need for adjustment, repair or replacement of the implant through further injections.

The combination of Silverman and Bley discloses the invention as claimed, see rejection supra; however the combination does not disclose expressly that the bulking prosthesis has a width approximately equal to a width of the opening at the distal end of the tubular instrument. Instead, the combination indicates that the bulking prosthesis occupies the entire width of the distal end of the tubular instrument as shown in Fig. 2 of Bley. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to use a bulking prosthesis having a width approximately equal to a width of the opening at the distal end of the tubular instrument because Applicant has not disclosed that the bulking prosthesis width being approximately equal to a width of the opening at the distal end provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art would have expected Silverman's and Bley's delivery system and applicant's

invention, to perform equally well with either the bulking prosthesis taught by the combination of Silverman and Bley or the claimed bulking prosthesis having a width approximately equal to a width of the opening at the distal end of the tubular instrument because both would perform the same function of, following injection, forming a bulked structure that will induce constriction of a sphincter. Alternatively, the "bulking prosthesis" of the instant application may be interpreted as the combination of the unswelled solid polymers and the carrier liquid as disclosed by Bley since Applicant has not provided any further limitations to the "bulking prosthesis."

Therefore, at the time of the invention it would have been prima facie obvious to modify Silverman and Bley to obtain the invention as specified in claims 1 and 9 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of Silverman and Bley.

4. Claims 5 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Silverman et al. (Patent 6251063 B1) and Bley (US 6592859 B1) as applied to claim 4 above, in view of Silverman et al. (Patent 6358197 B1). The combination of Silverman et al. ('063) and Bley teaches the method of claim 4, as described above, comprising implanting a bulking prosthesis, which enlarges after implantation, in a pocket formed between the mucosa and muscle tissue proximate an anal sphincter. This combination does not teach the use of vacuum pressure. Silverman et al. ('197) teaches a method of implanting a bulking prosthesis comprising drawing the mucosa (246, 248) away from musculature (252,254) underlying the submucosa (256) by applying vacuum pressure (as described in lines 1-3 of the

abstract and lines 53-57 of column 14) through a conduit within an instrument to the mucosa (246,248) (as seen in Figures 6 and 7). It would have been obvious to one of ordinary skill in the art at the time of the invention to practice the method similar to that taught by the combination of Silverman et al. ('063) and Bley using vacuum pressure similar to the method taught by Silverman et al. ('197) because a vacuum allows a physician to shape the target tissue into protrusions and form implants in the protrusions which have a consistent and predetermined size and shape (as described in lines 51-54 of column 20 of Silverman et al. ('197)).

5. Claims 9-12 are rejected under 35 U SC 103(a) as being unpatentable over Silverman et al (Patent 6358197 B1) in view of Sawhney (PGPUB 2001/0046518 A1) and further in view of Bley (US 6592859 B1). Silverman et al ('197) teaches a system comprising: a needle (96,52) to make a hole through a mucosa (246) proximate to an anal sphincter (as described in lines 42-43 of column 20); a tubular instrument (96, 52) having a distal end and an opening (108) at the distal end (96b); and a pushing agent (180) to push a bulking prosthesis (337) through the tubular instrument (96, 52) and through the hole in the mucosa (246, 248) (as described in lines 47-53 of column 17) (as seen in Figures 3, 4, 6, 20 and 26), a source of vacuum pressure (220) (as described in lines 29-31 of column 13); and a conduit (92,232) (as described in lines 63-65 of column 4, and lines 3-5 of column 14) to deliver the vacuum pressure from the source (220) to the mucosa (246, 248) (as seen in Figure 6) (as described in lines 18-25 of column 16), wherein the conduit (92,232) comprises a distal end with a cavity (227) at the distal end to receive the mucosa (246, 248) when the cavity (227) is positioned

proximate to the mucosa (246, 248) and the vacuum pressure is delivered to the mucosa (246) (as seen in Figure 6) (as described in lines 18-25 of column 16), and wherein the tubular instrument (96, 52) comprises the needle (96, 52) (as seen in Figures 3, 4, and 6). However, Silverman ('197) does not teach that the bulking prosthesis (337) is in a miniature state at the time of implantation and assumes an enlarged state after implantation, instead Silverman teaches that the bulking prosthesis may be a precipitate formed from an injectable solution (as described in lines 62-67 of column 17 and in lines 1-28 of column 18).

Sawhney teaches a bulking prosthesis as described above, wherein the bulking prosthesis is in a miniature state at the time of implantation and assumes an enlarged state after implantation (as described in lines 4-6 of paragraph [0026]).

Bley teaches a method of implanting a bulking prosthesis in the tissue of a patient, as described above, wherein Bley further teaches that using solid materials for a bulking prosthesis has an advantage in that their final size is more predictable because they swell to a size equal to that of the cavity created during the injection, thus they don't migrate away from the injection site (as described in lines 47-67 of column 6), as described above. It would have been obvious to one of ordinary skill in the art at the time of the invention to use a bulking prosthesis similar to that of Sawhney in a method similar to that of Silverman ('197) in order to treat fecal incontinence in view of the teachings of Bley because a bulking prosthesis similar to that of Sawhney has a more predictable size after injection, is permanent and won't degrade or be absorbed by the

body like collagen and silicone, thus eliminating the need for adjustment, repair or replacement of the implant through further injections.

6. Claims 13-15 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Johnson et al. (US 6338345). Johnson et al. teaches a device comprising a bulking prosthesis comprising a hydrogel (as described in lines 31-39 of column 15) that assumes one of a miniature state and an enlarged state, and assumes a desired shape after it has expanded into the enlarged state (as described from line 54 in column 15 to line 29 of column 16), wherein the bulking prosthesis may be formed in a variety of shapes and sizes including a cylindrical, toric or rod shape, wherein optimal dimensions are patient specific (as described from line 34 in column 6 to line 18 in column 7). While Johnson et al. does not expressly teach that the bulking prosthesis may be implanted around or within the anus of a patient, this limitation in the claim is considered to be directed towards the intended use of the device wherein the device of Johnson et al. is capable of performing the intended use.

7. Claim 16 is rejected under 35 U.S.C. 103(a)as being unpatentable over Johnson et al. (US 6338345) as applied to claim 13, in view of Capecchi et al. (US 5489300 A). Johnson et al. teaches a bulking prosthesis to a patient, as described above, but does not teach the use of Dacron mesh. Capecchi et al. teaches the use of Dacron mesh to surround an implant in order to promote cellular growth around the implant (as described in lines 37-38 of column 1). It would have been obvious to one having ordinary skill in the art at the time of the invention to surround a bulking prosthesis

comprising a hydrogel similar to that of Johnson et al. with Dacron mesh similar to the prosthesis of Capecchi et al. in order to promote tissue ingrowth around the prosthesis to secure said bulking prosthesis within the implantation site (as described in lines 34-36 of column 1 of Capecchi et al.).

8. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al. (US 6338345) as applied to claim 13, in view of Silverman (Patent 6251063 B1). Johnson et al. teaches a prosthesis to a patient, as described above, but does not teach the use of radiopaque materials. Silverman ('063) teaches a method comprising: implanting a bulking prosthesis (337,371) comprising a hydrogel, as described above, wherein said bulking prosthesis (337, 371)comprises radiopaque materials (as described in lines 10-13 of column 11 and in lines 15-19 of column 19). It would have been obvious to one of ordinary skill in the art at the time of the invention to combine a bulking prosthesis similar to that of Johnson et al. with radiopaque materials similar to those of the bulking prosthesis of Silverman ('063) in order to allow monitoring via x-ray or radiography of the bulking prosthesis after implantation (as described in lines 15-19 of column 19 of Silverman ('063)).

9. Claims 18-19 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al. (US 6338345) in view of Silvestrini (US 5824086 A). Johnson et al. teaches a device and method for delivering a bulking prosthesis to a patient, wherein said bulking prosthesis comprises a hydrogel (as described in lines 31-39 of column 15) that assumes one of a miniature state and an enlarged state, and assumes a desired shape after it has expanded into the enlarged state (as described from line 54 in column

15 to line 29 of column 16), wherein the bulking prosthesis may be formed in a variety of shapes and sizes including a rod shape, wherein optimal dimensions are patient specific (as described from line 34 in column 6 to line 18 in column 7), as described above, but does not teach that the bulking prosthesis has a sharpened tip nor that the bulking prosthesis is at least ten or twenty millimeters in length. Silvestrini teaches a device comprising a rod like bulking prosthesis having a sharpened tip (as seen in Figures 4-7 and 9), wherein said bulking prosthesis comprises a hydrogel (as described in lines 26-47 of column 6), wherein said sharpened tip comprises a conical tip and wherein said bulking prosthesis assumes an enlarged state in the presence of water (as described in lines 43-50 of column 6). It would have been obvious to one of ordinary skill in the art at the time of the invention to form a rod shaped bulking prosthesis similar to that of Johnson et al. with a conical sharpened tip similar to that of the prosthesis of Silvestrini in order to facilitate easy implantation of the bulking prosthesis into the tissue of the patient as the bulking prosthesis is in a miniature or "dried" state at the time of implantation, as sharpened conical tips were commonly used in the art at the time of the invention to ease surgical procedures. Furthermore, as described above, it would have been obvious to one having ordinary skill in the art at the time of the invention to form a bulking prosthesis similar to that of Johnson et al. with dimensions and configurations suitable to each patient (as described from line 34 in column 6 to line 18 in column 7 of Johnson et al.), therefore using a bulking prosthesis similar to that of Johnson et al. with a length of at least ten or twenty millimeters would have been an obvious design choice to one having ordinary skill in the art at the time of the invention to accommodate a

patient requiring a bulking prosthesis of that size (for example, a very tall patient who would inherently have larger organs than a smaller or shorter patient).

10. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Johnson et al. (US 6338345) and Silvestrini (US 5824086 A) as applied to claim 18 above, in view of Tu et al. (US 2002/0188308 A1). The combination of Johnson et al. and Silvestrini teaches a method for implanting a rod shaped bulking prosthesis in a miniature state at the time of implantation, said bulking prosthesis having a sharpened tip proximate to the tissue of a patient, wherein said bulking prosthesis is engaged with an application device and the step of withdrawing the application device after implantation, wherein said bulking prosthesis assumes an enlarged state after implantation, as described above. However, this combination does not teach that the bulking prosthesis comprises a helical thread. Tu et al. teaches a bulking prosthesis comprising a helical thread around the rod-like bulking prosthesis (as seen in Figures 32-34), wherein said bulking prosthesis comprises a hydrogel (as described in paragraph [0119]). It would have been obvious to one of ordinary skill in the art to make a bulking prosthesis similar to that of the combination of Johnson et al. and Silvestrini with helical threads similar to that taught by Tu et al. in order to aid in inserting said device into the tissue of a patient and to retain said prosthesis once implanted as is a commonly known advantage of threaded or screw-like implants used in the art (as described in lines 3-5 of paragraph [0162] of Tu et al.).

11. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tu et al. (US 2002/0188308) in view of Lat et al. (US 5741104 A). Tu et al. teaches a bulking

prosthesis comprising a sharpened tip and helical thread around the rod-like bulking prosthesis (as seen in Figures 32-34), wherein said bulking prosthesis comprises a hydrogel (as described in paragraph [0119]), however Tu et al. is silent as to the method of making said bulking prosthesis. Lat et al. teaches a method of making a screw shaped device, the method comprising providing a rod-like device, forming a sharpened tip on an end of said object and machining a helical thread around said device (as described from line 66 of column 4 through line 7 of column 5). It would have been obvious to one having ordinary skill in the art at the time of the invention to form a bulking prosthesis similar to that of Tu et al. using a method similar to that of Lat et al. as a design choice compared to other methods of forming screw shaped devices, in order to obtain the desired bulking prosthesis shape as taught by Tu et al.

12. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Tu et al. (US 2002/0188308 A1) and Lat et al. (US 5741104 A) as applied to claim 22 above, in view of Culpen et al. (US 5542799 A). The combination of Tu et al. and Lat et al. teaches a method of making a bulking prosthesis as described above, wherein said bulking prosthesis is implanted into the tissue of a patient wherein the bulking prosthesis is designed to resist movement away from the implantation site (as described in paragraphs [0155]-[0156]). However, this combination does not teach the formation of a slot in said prosthesis. Culpen et al. teaches a device comprising a sharpened tip, helical threading and a slot (as seen in Figures 1 and 4) (as described in lines 40-61 of column 2). It would have been obvious to one having ordinary skill in the art at the time of the invention to make a bulking prosthesis similar to that of the

combination of Tu et al. and Lat et al. with a slot similar to that of the device taught by Culpen et al. in order to enhance the ability of the bulking prosthesis to brace against the tissue of the patient once implanted (as described in the abstract and from line 62 of column 2 to line 37 of column 3 of Culpen et al.).

Allowable Subject Matter

13. Claims 25-28 are allowable over the prior art of record. The following is a statement of reasons for the indication of allowable subject matter: regarding claims 25-28, the prior art of record does not teach or fairly suggest a method for implanting a bulking prosthesis comprising implanting a rod-like bulking prosthesis in a miniature state at the time of implantation having a sharpened tip proximate to an anal sphincter, the bulking prosthesis engaged with an application device and withdrawing the application device, wherein the bulking prosthesis assumes an enlarged state after implantation.

Response to Arguments

14. Applicant's arguments filed 5 July 2007 with respect to the Information Disclosure Statement have been considered. The list of patents, publications and other information provided by Applicant was properly submitted on 31 October 2003, and considered by the Examiner.

15. Applicant's arguments filed 5 July 2007 with respect to the rejection of claims 1-12 under under 35 U.S.C. 103(a) as being unpatentable over Silverman ('063) in view of Bley ('859) have been fully considered but are moot in view of the new grounds of rejection under 35 U.S.C. 103(a) as being unpatentable over Silverman ('063) in view of Bley ('859); see rejection supra.

16. Applicant's arguments filed 5 July 2007 with respect to the rejection of claims 13-17 under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Johnson et al. ('345) have been fully considered and are not persuasive. Applicant contends that none of the shapes provided by Johnson have an inner radius as claimed. However, this argument is not persuasive. The claim recites that the inner radius of the partial cylinder (for instance, a cylindrical shape as disclosed at col. 6, lines 50-52 or a hydrogel rod as disclosed at col. 16, line 14) in order to tailor the device to a specific degree of closure based on the sphincter of the patient. Moreover, Johnson similarly teaches, as in the instant application, that the bulking prosthesis may be applied to a submucosal region of a lumen (col. 16, lines 42-47), thus necessitating the use of like dimensions. Therefore, it would have been obvious to one of ordinary skill in the art to produce a bulking device based on the specific features of the patient and the anatomical passageway necessitating closure or closing pressure. In view of the foregoing, the rejection of claims 13-17 under 35 U.S.C. 103(a) citing Johnson et al. (US 6338345) has been maintained.

17. Applicant's arguments filed 5 July 2007 with respect to the rejection of claims 18-21 under 35 U.S.C. 103(a) citing Johnson ('345) in view of Silvestrini ('086) have been fully considered and are not persuasive. Applicant contends that the modification of Johnson to include a conical sharpened tip as disclosed by Silverstrini is directly contradictory to the teachings of Johnson. However, this argument is not persuasive. Firstly, the language of claim 18 does not require a conical sharpened tip, but only a sharpened tip. Furthermore, Johnson teaches that a smooth, blunt atraumatic tip is preferred, but further teaches that the configuration of the bulking device may have sharp edges, thus not precluding the inclusion of a sharpened tip. While the disclosure may provide for a preferred configuration, others are also possible within the teachings of Johnson. In view of the foregoing, the rejection of claims 18-21 under 35 U.S.C. 103(a) citing Johnson ('345) in view of Silvestrini ('086) has been maintained.

18. Applicant's arguments filed 5 July 2007 with respect to the rejection of claims 22-23 under 35 U.S.C. 103(a) citing Tu (2002/0188308) in view of Lat ('104) have been fully considered but are not persuasive. Applicant contends that the combination fails to disclose that the bulking prosthesis assumes an enlarged state in the presence of water. However, this argument is not persuasive. Hydrogels are super-absorbent compositions, and thus expand in the presence of water. Therefore, the hydrogel as taught by Tu will assume an enlarged state in the presence of water. Moreover, it is noted that the claim language only provides that the "bulking prosthesis assumes an enlarged state in the presence of water," and not necessarily that this step is performed

in a method for manufacturing a bulking prosthesis, or that water is present. In view of the foregoing, the rejection of claims 22-23 under 35 U.S.C. 103(a) citing Tu (2002/0188308) in view of Lat ('104) has been maintained.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine D. Hopkins whose telephone number is (571) 272-9058. The examiner can normally be reached on Monday-Friday, 7 a.m.-3:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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